

# Notice of Allowability

## Application No.

10/682,331

## Examiner

Jon M. Lockard

## Applicant(s)

SHELTON ET AL.

## Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Amendment and Response filed 25 January 2007.
2. ☒ The allowed claim(s) is/are 1-6 and 9-12 (renumbered as claims 1-10).
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date 1/25/07, 3/12/07
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

**CHRISTINE J. SAOUD  
PRIMARY EXAMINER**

*Christine J. Saoud*

### **EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jie Zhou on 29 March 2007.

2. The application has been amended as follows:
3. Claims 7-8 have been cancelled without prejudice or disclaimer.
4. In claim 1, the phrase "an individual" has been deleted and the phrase --a human subject-- inserted therefor.
5. In claim 1, the phrase "the individual an effective" has been deleted and the phrase --the subject in need of such treatment an effective-- inserted therefor.
6. In claim 1, the phrase "the individual is treated" has been deleted and the phrase --the subject is treated-- inserted therefor.

### ***Information Disclosure Statement***

7. The information disclosure statements (IDS) submitted on 01 January 2007 and 12 March 2007 have been considered by the Examiner.

### REASONS FOR ALLOWANCE

8. The following is an examiner's statement of reasons for allowance:

9. The closest prior art is Owolabi et al. (J. Pharmacol. Exp. Ther. 289(3):1271-1276, 1999). Owolabi et al. teach administration of ALE-0540, a nerve growth factor receptor antagonist which inhibits binding of NGF to the NGF receptor TrkA, produces antiallodynia in a rat model of neuropathic pain, and blocks tactile allodynia in an inflammatory pain model in rats. However, the state of the art at the time the application was filed teaches that the pathophysiology, as well as neurochemical and cellular characteristics of post-operative (i.e., incisional or postoperative) pain are unique when compared with both inflammatory and neuropathic pain (See Honore et al. Behavioral Brain Research. 167:355-364, 2006 (Reference 11 on IDS filed 1/12/07); Jarvis et al. Proc. Natl. Acad. Sci. USA 99(26):17179-17184, 2002; Joshi et al. Pain. 123:75-82, 2006; Pogatzki et al. Anesthesiology. 96:1153-1160, 2002 (Reference 265 on IDS filed 7/6/04); Yamamoto et al. Brain Research. 909:138-144, 2001 (Reference 312 on IDS filed 7/6/04). Based on the substantial differences between post-surgical pain and both inflammatory and neuropathic pain, one of ordinary skill in the art would not have been motivated to use an agent that reduces inflammatory or neuropathic pain for the treatment of post-surgical pain at the time the invention was made. Moreover, because of the pathophysiological, neurochemical, and cellular characteristic differences of post-surgical pain as compared to both inflammatory and neuropathic pain, the skilled artisan would not have had a reasonable expectation of success of using an agent that reduces inflammatory or neuropathic pain for the treatment of post-surgical pain.

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10. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 7:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback**, can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Jon M. Lockard, Ph.D.  
March 30, 2007

**CHRISTINE J. SAOUD  
PRIMARY EXAMINER**

*Christine J. Saoud*